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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,985	11/28/2000	Philip Michael Savage	674544-2001	8380

7590

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EXAMINER

DECLOUX, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 11/04/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,985

Applicant(s)

SAVAGE, PHILIP MICHAEL

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-18, 23, 24 and 26-29 is/are rejected.
- 7) ☐ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's request to make the application "special" is acknowledged and as such the instant application will be handled as expeditiously as possible. With regard to Applicant's request for an interview if the instant application is not in condition for a first office action allowance is denied because the examiner prefers to have a written record of the prosecution history. However, an interview will be granted after mailing of this office action at Applicant's request.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-18, 23-24 and 26-28, and newly added claim 29, in Paper No. 11, filed 7-31-02, is acknowledged. The traversal is on the ground(s) that the claims of Groups I-V all relate to a complex comprising HLA class I molecule or fragment thereof and that any search and examination would be co-extensive for the claims of Groups I-V. This is not found persuasive because though the searches for each group overlap, they would not be co-extensive, as evidenced by their overlapping but not co-extensive classifications. Therefore, there would be an undue search burden on the examiner to search Groups I-V in one application.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 19-22 and 25 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 6/5/1998 and 4/12/99. It is noted, however, that applicant has not filed a certified copy of the 9812227.8 or 9908333.9 applications as required by 35 U.S.C. 119(b).

Drawings

4. New corrected drawings are required in this application because of the reasons outlined on the attached Drawing Review. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

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All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

C. Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

5. The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required. See specifically the last paragraph on page 4, the last full paragraph on page 5, and line 4 of page 6.

Claim Objections

6. Claim 1 is objected to because of the following informalities: an article is missing before the phrase "attaching means" in line 3. Appropriate correction is required.

7. Claim 12 is objected to because of the following informalities: a demonstrative adjective is missing between the words peptide and comprises in line 2. Inserting the word "that" would overcome the objection. It is noted that the preliminary amendment filed 11-28-00 directing the insertion of the word "that" after the word "peptide" in line 2 of claim 12 was not entered because said line contains the word "peptide" twice. Appropriate correction is required.

8. Claim 16 is objected to because of the following informalities: a demonstrative adjective is missing between the words peptide and comprises in line 2. Inserting the word "that" would

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overcome the objection. It is noted that the preliminary amendment filed 11-28-00 directing the insertion of the word "that" after the word "peptide" in line 2 of claim 16 was not entered because said line contains the word "peptide" three times. Appropriate correction is required. Claim 16 is objected to because of the following informalities: an article is missing before the phrase "recognition peptide" in line 2

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 13, 23-24 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 13 recites the broad recitation an Epstein-Barr

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virus peptide, and the claim also recites an Epstein-Barr virus peptide comprising the RAKFFQLL epitope of the lytic protein BZLF1, which is the narrower statement of the range/limitation.

Further regarding claim 13, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Further regarding Claim 13 is indefinite in its recitation of the phrase "A complex as claimed in claim 11 appended to claim 10, or claim 12," because it is not clear how a complex can be appended to a claim. Appropriate correction is required.

12. Regarding claim 23 and dependent claims 24 and 28, the phrase "such as" in lines 3, 4 and 6 of claim 23 renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

13. Regarding claim 26 and dependent claims 27 and 29, the phrase "such as" in lines 3, 4 and 5 of claim 26 renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

14. Claim 29 recites the limitation "said compound" in line 3. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method steps which describe the method of preparing the recited composition.

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 23-24, 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims encompass a pharmaceutical composition and a pharmaceutical pack or kit comprising a complex recited in claims 11, 15-16 and 23. The instant specification provides only in vitro exemplifications of the recited complexes. The in vivo uses of the recited complexes is unpredictable as evidenced by Applicant's own post-filing date reference (Ogg et al British Journal of Cancer 2000, 82(5):1058-1062) which teaches that the feasibility of employing the recited complexes in vivo needs to be assessed. Ogg et al further teaches that the immunogenicity of avidin or other components of the targeting complex may limit repeated use, that there is no experience to date on the administration of recombinant HLA molecules in humans, and that though unlikely, the complexes may be sequestered in lymphoid areas, and that due to variability in TAA expression by tumors, some tumor cell may not be targeted by the antibody and lysed directly (see entire article, especially page 1061). *In re Fisher*, 1666 USPQ 19 24 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Without such guidance, it would require undue experimentation for one of skill in the art to use the recited products for in vivo use, as encompassed by the instant claims, without further guidance from the specification. See *Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-7, 9-12 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mage et al U.S. Patent 5,026,785.

20. '785 teaches water soluble multivalent heteroligating antibody conjugates capable of binding cells of different MHC haplotypes, as well as heteroconjugates of anti-class I MHC antibodies and soluble Class I MHC molecules. '785 teaches that these conjugates have been used to coat murine tumor cells, and can be used as immunotoxins, tumor labeling reagents or vaccines by mixing any of a variety of biotinylated antibodies or toxins or biotinylated proteins with streptavidin or avidin modified polyacrylamide (see entire patent especially column 1 and column 4, lines 14-20, column 8, lines 53-62). The open language of the instant claims is noted. Therefore, the referenced teachings anticipate the claimed invention.

21. No claim is allowed.

22. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821.

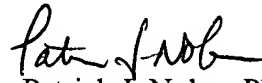
The examiner can normally be reached on M-F 8:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner
October 30, 2002


Patrick J. Nolan, Ph.D.
Primary Patent Examiner,
Group 1640